

Notice of Allowability

Application No.

10/089,498

Examiner

Young J. Kim

Applicant(s)

LEE ET AL.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment received on January 31, 2007.
2. ☒ The allowed claim(s) is/are 1,3-6,8-26,34 and 35.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Young J. Kim
Primary Examiner
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4-13-07

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Jamie Greene on April 13, 2007.

The application has been amended as follows:

In the Claims:

Claims 27-33 have been canceled.

1. (Currently Amended) A method of carrying out an amplification reaction, said method comprising supplying to a reagent well in a disposable unit, a reaction mixture comprising: (a) a sample which contains or is suspected of containing a target nucleic acid sequence; (b) primers, nucleotides and enzymes required to effect said amplification reaction; and (c) a buffer system, wherein the pH of said buffer system is from 8.7 – 9.0, and subjecting the disposable unit to thermal cycling conditions such that any target nucleic acid present within the sample is amplified; wherein the disposable unit comprises a thermally conducting layer and a facing layer having one or more reagent wells up to 1000 microns in depth defined therebetween, and wherein said reaction mixture further comprises a detergent and/or a blocking agent.

3. (Currently Amended) A method of carrying out an amplification reaction, said method comprising supplying to a reagent well in a disposable unit, a reaction mixture comprising: (a) a sample which contains or is suspected of containing a target nucleic acid sequence; (b) primers, nucleotides and enzymes required to effect said amplification reaction;

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and (c) a buffer system, wherein the pH of said buffer system is at or above ¹8.8, and subjecting the disposable unit to thermal cycling conditions such that any target nucleic acid present within the sample is amplified; wherein the disposable unit comprises a thermally conducting layer and a facing layer having one or more reagent wells up to 1000 microns in depth defined therebetween, and wherein said reaction mixture further comprises a detergent and/or a blocking agent.

4. (Currently Amended) The method according to claim 1 or 3, wherein the buffer system comprises from 30-70mM Tris HCl.

5. (Currently Amended) The method according to claim 4, wherein the buffer system comprises about 50mM Tris HCl, pH 8.8 at 25°C.

In claims 6, 8, 9, 13-16, 18, 19, 21, 22, 25, and 26, the phrase, "The method according to claim 1" has been replaced with the phrase, "The method according to claim 1 or 3".

Examiner's Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The combination of amplification reaction mixture comprising a buffer system having a pH of 8.7-9.0 or at least 8.8 along with a blocking agent and/or detergent, produced in the disposable unit of the invention shows a surprisingly successful amplification (page 4, lines 12-16; page 18-19, Tables 1-3) in amplification reaction vessels made of materials which may inhibit nucleic acid amplification reaction, as arguments presented on page 8, bottom paragraph through page 9, 1st paragraph, of Applicants' Response.

¹ I added "at or above" because the example clearly has an example at pH of 8.8 as well. This also allows multiple dependencies to fit nicely.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the

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status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Primary Examiner
Art Unit 1637
4/13/2007

**YOUNG J. KIM
PRIMARY EXAMINER**

YJK